K061978 (0 1 of 2)

EBI, L.P.'s
Line Extension to the Array® Spinal System

AUG 1 1 2006

SUBMITTER:	EBI, L.P.
ADDRESS:	100 Interpace Parkway Parsippany, NJ 07054
PHONE:	(973) 299-9300
FAX:	(973) 257-0232
CONTACT PERSON:	Jennifer P. Harakal
DATE PREPARED:	July 12, 2006
TRADE NAME:	Array® Spinal System
COMMON NAME:	Spinal Fixation Device
CLASSIFICATION NAME:	Spondylolisthesis Spinal Fixation Device Spinal Intervertebral Body Fixation Orthosis Spinal Interlaminal Fixation Orthosis
PREDICATE DEVICES:	-EBI® Array® Spinal System (formerly referred to as 'Top Loading MAS Spinal Fixation System') -EBI® Webb Morley Spine System

INTENDED/INDICATIONS FOR USE:

The Array® Spinal System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use; degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e., scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudarthrosis, and failed previous fusion.

TECHNOLOGICAL CHARACTERISTICS:

Performance Testing

Performance data comparatively evaluating the modified system to its predicate devices demonstrate that the proposed system adequately meets the requirements established in design specifications for its mechanical performance. The design requirements were established based on those of the previously cleared predicate devices.

Substantial Equivalence

The modified Array® Spinal System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and basic principles of operation. This premarket notification is being submitted to address a line extension to the existing Array Spinal System. As demonstrated by supporting performance data, these technological differences do not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

EBI, L.P.
% Ms. Jennifer P. Harakal
Regulatory Affairs Specialist
100 Interpace Pkwy
P.O. Box 346
Parsippany, New Jersey 07054

Re: K061978
Trade/Device Name: Array® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: MNH, MNI, KWP, KWQ, NKB
Dated: July 12, 2006
Received: July 13, 2006

Dear Ms. Harakal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to

begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehler
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K061978

Device Name: Array® Spinal System

Indications for Use:

The Array Spinal System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use; degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e., scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudarthrosis, and failed previous fusion.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brechner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061978